



Daniel M. Silver
Wilmington Office Managing Partner

T. 302-984-6331
F. 302-691-1260

dsilver@mccarter.com

McCarter & English, LLP

Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801-3717

www.mccarter.com

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VIA CM/ECF

The Honorable Joseph F. Bataillon
Roman L. Hruska Federal Courthouse
111 South 18th Plaza, Suite 3259
Omaha, NE 68102

The Honorable Eleanor G. Tennyson
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801

**Re: *Astellas Pharma Inc., et al. v. Lupin Ltd., et al.*, C.A. No. 20-1589-JFB-EGT
 Astellas Pharma Inc., et al. v. Lupin Ltd., et al., C.A. No. 23-819-JFB-EGT
 Astellas Pharma Inc., et al. v. Lupin Ltd., et al., C.A. No. 24-939-JFB-EGT
 Astellas Pharm Inc., et al. v. Zydus Pharmaceuticals (USA) Inc., No. 24-940-JFB-EGT
 Astellas Pharma Inc., et al. v. Lupin Ltd., et al., C.A. No. 24-1068-JFB-EGT
 Astellas Pharm Inc., et al. v. Zydus Pharmaceuticals (USA) Inc., No. 24-1069-JFB-EGT**

Dear Judge Bataillon and Judge Tennyson,

Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, “Astellas”), along with Defendants Lupin Ltd., Lupin Pharmaceuticals, Inc. (collectively, “Lupin”), Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited (collectively, “Zydus”) (collectively with Lupin, “Defendants”) respectfully submit this cover letter as the Court requested in its recent Orders. CA. No. 20-1589, D.I. 652; C.A. No. 24-939, D.I. 24; C.A. No. 24-940, D.I. 20; C.A. No. 24-1068, D.I. 19; C.A. No. 24-1069, D.I. 17. The parties have exchanged competing schedules and conferred on January 2. The parties agreed that to adequately try the ’451, ’189, ’409 patents and remaining ’780 patent infringement and damages issues, the parties require a seven-day trial. The parties were able to agree on the deadlines for Paragraph 4 disclosures under the Default Standard for Discovery and the deadlines related to claim construction, but were unable to reach agreement regarding the remaining deadlines. The parties’ competing proposals are set forth in Attachment A, and a short position statement from Astellas and Defendants follows. The parties are available should the Court have any questions regarding their competing proposals. If not, the parties respectfully request that the Court enter a schedule at its earliest opportunity. Once the Court provides guidance on the schedule, the parties will submit a schedule using the Court’s form scheduling Order.

Astellas’s Position

Last year, Zydus and Lupin took the rare step of launching “at risk” during the pendency of patent infringement actions. In doing so, Zydus and Lupin caused untold harm to Astellas’s market for its first-in-class Myrbetriq treatment. Every day since then, Astellas’s market share continues to face erosion due to Zydus and Lupin’s generic copies of Myrbetriq. Astellas has thus worked hard to move the ’451 patent action towards the scheduled September 2025 trial date, in order to obtain an injunction against Zydus and Lupin and stymie the harm.

In view of the Court’s recent Order, CA. No. 20-1589, D.I. 652, Astellas proposes pushing back this trial date to December—taking on another two months of damage—such that all four patents may be tried in a single jury trial to conserve judicial resources.¹ See Attachment A. This proposal accounts for the extensive discovery that has already taken place in the ’780 and ’451 patent actions: All of the inventors’ depositions have been taken, twice; Astellas has already responded to 45 interrogatories, 28 requests for admission, and 97 requests for production covering both technical and damages queries; and the Court has resolved any claim construction disputes concerning the ’451 patent and ’780 patent.² Given that the ’189 and ’409 patents are family members of the ’451 and ’780 patents, the parties should be able to quickly complete any remaining discovery and prepare for trial before the end of 2025. Astellas’s schedule furthermore begins summary judgment briefing four months before trial, and provides two months before the trial date for the Court to rule on any such motions—ill-suited though they may be to resolution on summary judgment, given the technical, highly fact-specific inquiries that drive the issues in this case. Despite acknowledging, below, that “there is no question that the parties have already conducted significant discovery,” Zydus and Lupin now propose pushing the September trial out by *eight months* to May 2026, which is contrary to their prior representation to the Court that they would be trial-ready in February 2026. See 11/12/2024 Hearing Tr. at 22:18–24:12 (Defendants representing to Court that they “could foresee a schedule where all three of them [the ’451, ’409 and ’189 patents] go to trial in maybe February 2026,” and “including damages on the ’780.”). Even this February 2026 date is unfairly prejudicial and thus unworkable for Astellas, due to the hardships posed by having to wait a further two months—on top of the proposed compromise 3-month delay—for trial. The May 2026 trial date Defendants now propose only exacerbates the prejudice to Astellas’s ability to remove the generics from the market in a reasonable amount of time. And although Defendants clearly had a case schedule in mind at the time they proposed a consolidated trial in February 2026, they never provided that schedule to Astellas—despite Astellas’s request for it—and now contend that their own prior proposal is unworkable.

¹ Defendants characterize this as an “about face” from Astellas’s statement that “[w]e’re flexible on fast or slow,” at the November 2024 hearing. There has been no “about-face.” Astellas proposed all of the patents—including all issues as to the ’780 patent—proceed to a jury trial in September 2025 (i.e. slow). D.I. 640 at 1. In the alternative, Astellas had proposed a schedule contemplating a June 2025 trial on the ’780 patent alone (i.e., fast). D.I. 633. And Astellas’s proposed December 2025 trial date is far slower than its sought-after June 2025, ’780 patent trial date.

² Defendants’ argument that “Astellas’s schedule contemplates that witnesses may be deposed multiple times” is incorrect. As has been stated repeatedly on meet and confers with Defendants, Astellas does not intend to re-depose witnesses on the same topic. Nor will Astellas agree to provide its own witnesses repeatedly; to the contrary, Astellas’s schedule accounts for the fact that many witnesses have already been deposed.

Zydus and Lupin have raised a variety of excuses for why they have pushed out the originally proposed February 2026 trial date, none of which withstand scrutiny. *First*, Defendants allege that Astellas's schedule provides "less than one month" for substantial completion of document production, complaining about written discovery regarding the '189 and '409 patents. If the patents are so different that they require substantially different document production, then these cases should not be consolidated into one schedule, given the prejudice to Astellas for having to await its day in Court, and the '451 patent should proceed to trial in September 2025 per the current schedule. Defendants notably fail to identify any substantial document production they anticipate needing to provide or obtain as to either patent: That is because no such substantial production is necessary. Astellas, for its part, does not anticipate much, if any, additional document collection or production unique to the '189 and '409 patents.

Defendants' position also ignores the amount of discovery that has proceeded since the parties' last conference before the Court. All parties have continued to produce documents, and an additional seven depositions have occurred. Any delay is moreover of Defendants' own doing, and Defendants should not profit from it. For instance, Astellas has been asking for January dates for two of Zydus's witnesses since December 2, 2024, and has only just heard back from Zydus today. Astellas planned to make former Astellas employee Mark Schwitzenberg available for deposition on December 17, 2024, but Defendants refused to take it then, and on Monday rejected a second proposed date. On the morning of January 4, Defendants also cancelled a deposition set to occur on January 8 due to a stomach bug, despite the fact that Defendants have four law firms between them and had four days to find a replacement. Defendants should not be rewarded for dragging their feet in discovery, nor use their delay tactics now to justify a later trial date.

Second, Defendants claim that claim construction may pose a challenge—but the Court has already resolved any claim construction disputes regarding two of the patents, and, given Defendants' repeated refrain that the other two patents are closely-related family members, any remaining claim construction disputes should be limited and can be resolved in parallel with other case activities. The potential for claim construction disputes should not derail the schedule and does not mandate the unnecessarily lengthy schedule Defendants propose.

Third, Defendants have alleged on the parties' meet and confer that they have other cases that *might* end up with *March or April* 2026 trial dates. But Astellas confirmed on the parties' January 2 meet and confer that Defendants have no presently scheduled trials in February 2026, and Defendants did not indicate they have any trials in December 2025 or January 2026.

Defendants have moreover sought to inject obviousness back into the '780 patent action, which is not in keeping with the Court's Order, or Defendants' own stipulations in this case. CA. No. 20-1589, D.I. 652 at 1 ("If the Court determines the '780 Patent is valid, the parties will try *infringement and damages* to a jury."), 6 (quoting Federal Circuit's mandate). Issue and claim narrowing happened throughout the '780 patent action, and Defendants have never identified any newly arising facts that warrant resurrection of their obviousness defenses, unlike with respect to Astellas's still-live infringement and damages claims. Given the Court's decision to resolve the

question of validity on the record created during the February 2023 bench trial, obviousness is not a defense in the '780 patent action.

Finally, Defendants, for the first time at 2 pm today, provided Astellas with their proposal for “an additional: (1) 10 common interrogatories; (2) 10 individual interrogatories; (3) 25 common requests for production; and (4) 25 hours for deposition, to accommodate additional discovery related to the '189, '409, and '780 patents.” Consistent with Astellas’s position *and* Defendants’ statement that “there is no question that the parties have already conducted significant discovery” and their wish to avoid further burdening fact witnesses, Astellas does not believe that such extensive additional discovery is warranted. Nor should the limited additional damages and infringement supplements relevant to the '780 patent be lumped in with the '189 and '409 patents.

Instead, Astellas proposes limited discovery as follows: (1) 5 common interrogatories and 5 individual interrogatories; (2) 10 common requests for production; (3) 15 requests for admission; and (4) 25 deposition hours. Astellas proposes that any discovery as to the '780 patent be limited to damages and new information concerning infringement based on Defendants’ launch.

For the foregoing reasons, Astellas respectfully submits that the Court should enter Astellas’s schedule as set forth in Attachment A, which contemplates a consolidated trial in December 2025.

Defendants’ Position

Astellas’s complaints about prejudice and damages belie the facts of this case. At the time Defendants’ launched their ANDA products: (1) Astellas had granted Defendants licenses and early entry dates in March and April 2024 in connection with the patents asserted by Astellas in the first mirabegron patent litigation; (2) the '780 patent had been found invalid; (3) Astellas’s preliminary injunction motion regarding the '451 patent had been denied because the patent was found substantially likely to be invalid; and (4) the '189 and '409 patents had yet to issue. In other words, Defendants launched their products “at-risk” under licenses and rulings from this Court indicating that Astellas could not be harmed at the time of launch. Now late in the game, after obtaining two additional patents and filing four new lawsuits, Astellas seeks to rush the parties and the Court to trial on four sets of patent claims that are substantially related but require unique assessments of validity and infringement.

Astellas’s insistence on a compressed case schedule is an about face from its representation at the Court’s November 12, 2024 hearing that “[w]e’re flexible on fast or slow,” when commenting on the length of the proposed schedule. (C.A. 20-1589-JFB-EGT, Nov. 12, 2024 Hearing Tr. at 37:11.) Defendants’ proposed schedule permits for an orderly completion of fact and expert discovery without the need for potential repetitive depositions and supplemental expert reports. Defendants’ proposal also provides the Court with time sufficient to consider any dispositive motions—and the invalidity of the '780 patent under Section 112—in advance of commencement

of a jury trial on at least the '451, '189, and '409 patents (and potentially infringement, obviousness,³ and damages for the '780 patent).

Astellas's compressed schedule is unworkable, inefficient and will impose undue burden on the Court and the parties. For example, Astellas's proposed schedule sets a deadline for substantial completion of document production on February 4, 2025, less than one month from now even though the parties have served no written discovery regarding the '189 and '409 patents. Given that Astellas has refused to state that it will not be seeking additional written or document discovery from Defendants regarding any of the four patents at issue, that deadline appears unworkable on its face.

Astellas's schedule contemplates that witnesses may be deposed multiple times. Astellas emphasized during the parties' January 2, 2025 meet-and-confer that it wishes to complete all of the depositions it has currently noticed with regard to the '451 patent and then potentially bring some of those same witnesses back for a third or fourth deposition on an ad hoc, as needed, basis with respect to the other patents. This approach is both inconsistent with the Court's orders to consolidate the cases for discovery purposes and unduly burdensome for the fact witnesses. Many of the parties' witnesses have already been deposed twice, or even three times, with Astellas repeating questions it asked of the same witnesses over five years ago. (*See* C.A. No. 23-819-JFB-EGT, D.I. 393 at 3.). There can be little doubt that the parties will be serving additional written discovery and deposition notices, including under Fed. R. Civ. P. 30(b)(6), that may implicate topics relevant to these same witnesses.

Defendants' proposed schedule permits the parties to complete *Markman* briefing before proceeding with expert reports, which allows the experts to address the parties' claim construction positions, and likely the Court's final constructions, before expert discovery closes. Astellas's proposed schedule would intertwine expert discovery with claim construction and make opening expert reports due before Defendants even submit their final claim construction brief with expert discovery closing potentially before the Court has issued a claim construction ruling.

Consistent with the Court's Orders, Defendants include in their proposed schedule deadlines to finalize all written discovery and deposition notices. The first of Astellas's serial patent infringement cases against Defendants regarding the same mirabegron ANDA products was filed in 2016 and there is no question that the parties have already conducted significant discovery, especially with respect to the development of both Defendants' ANDA products and Astellas's Myrbetriq product. These deadlines are needed so that the parties can move forward on a definite

³ While Defendants filed a stipulation agreeing not to raise obviousness defenses in the bench trial held in C.A. 20-1589-JFB-EGT, Defendants intend to seek relief from the Court given that their choice not to raise those defenses at that time was predicated on the limitations set forth by the Court for timing and structure of that specific bench trial and the evidentiary record in existence at that time.

schedule without already overburdened witnesses needing to sit for additional unnecessary depositions.

The Court's Order directed the parties to submit a schedule including motion practice. *See* C.A. No. 20-1589-JFB-EGT, D.I. 652 at 10. Defendants anticipate significant dispositive and *Daubert* motion practice before the final pretrial conference. Defendants' schedule builds in at least sixty days for the Court to consider these motions while still providing for dispositive motions to be filed less than one year after the parties' provide their initial infringement and invalidity contentions on the newly added '189 and '409 patents. Despite representing to the Court that Astellas would work with Defendants to provide the Court sufficient time to consider summary judgment motions (*see* C.A. No. 20-1589-JFB-EGT, Nov. 11, 2024 Tr. at 37:11-14), Astellas's schedule would provide the Court with approximately one month to rule on these motions before the final pretrial conference.

Defendants are not opposed to coordination of the discovery schedules in the *MSN* and *Ascent* cases with their own, but given that those cases will not be going to a jury, there does not seem to be an ability to coordinate trial. Defendants also request that the Court revise the current Scheduling Order in C.A. No. 23-819-JFB-EGT (D.I. 280) to include an additional: (1) 10 common interrogatories; (2) 10 individual interrogatories; (3) 25 common requests for production; and (4) 25 hours for deposition, to accommodate additional discovery related to the '189, '409, and '780 patents.

For these reasons, Defendants request that the Court enter their proposed schedule.

Respectfully submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

cc: Counsel of Record for Zydus and Lupin (via CM/ECF and E-Mail)